Immunocept, LLC, et al v. Fulbright & Jaworski Doc. 73

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF TEXAS
AUSTIN DIVISION

FILED
MAR 13 2006
CLERK, U.S. DISTRICT COURT
WESTERN DISTRICT OF TEXAS
BY ______ DEPUTY CLERK

IMMUNOCEPT, LLC, PATRICE ANN LEE AND JAMES REESE MATSON Plaintiffs, v. FULBRIGHT & JAWORSKI, LLP Defendant.	§ § § § § § § § § § § §	CAUSE NO. A 05 CA 334 SS

PLAINTIFFS' REPLY BRIEF IN SUPPORT OF ITS OBJECTIONS TO DEFENDANT'S PROPOSED EXPERT TESTIMONY OF JOHN R. KIRK

I
INTRODUCTION

A. Fulbright & Jaworski Ignores the Facts *In This Case*

To escape liability for letting an unsupervised junior attorney radically narrow Immunocept's patent claims, Fulbright & Jaworski needs to convince the Court that it had no other reasonable alternatives that might overcome prior art cited by the patent Examiner. Immunocept has suggested many such alternatives, including reliance on the claim preamble, or amendment to include a negative limitation, each of which is plainly permitted under U.S. patent law doctrine. This motion arises because Fulbright & Jaworski's expert Kirk will, unless this motion is granted, testify contrary to that well established doctrine.

73

Dockets.Justia.com

The main theme of Fulbright & Jaworski's opposition seems to be that such doctrine might be applicable in some circumstances, but *not in this case.* Fulbright & Jaworski argues, for example, that the facts here make it inappropriate to rely on the claim preamble to distinguish prior art. Far from justifying Kirk's departure from settled law, this new argument actually compounds Kirk's error by getting the facts wrong as well.

The record is clear that *in this case* Fulbright & Jaworski did rely on the claim preamble to provide a distinction. *In this case* Fulbright & Jaworski filed an amendment to distinguish the Okamoto reference based upon the content of the claim preamble. *In this case* Fulbright & Jaworski argued the content of the preamble as if it were limiting on the claim scope. *In this case* Fulbright & Jaworski relied on the very doctrine that it now denies is applicable. All this is plainly visible and beyond dispute in the written records of the Patent and Trademark Office. As shown below, Kirk's departure from the law and Fulbright & Jaworski's departure from the undisputed facts require exclusion of Kirk's testimony.

II.
LEGAL ANALYSIS

B. Kirk's Statements that Fulbright & Jaworski Could Not Have Argued that the Preamble of Claim 1 is Limiting are Contradicted by Federal Circuit Precedent and by Fulbright & Jaworski's Own Actions During the Prosecution of the 418 Patent.

The *Catalina Marketing* case discloses both the general principles that are used in the context of an infringement or invalidity dispute to determine whether a preamble is limiting (in the absence of explicit arguments during prosecution regarding the preamble), and the rule that a preamble will always be limiting *if the applicant argues that it is during prosecution of the patent.* Again:

> ...[C]lear reliance on the preamble during prosecution to distinguish the claimed invention from the prior art transforms the preamble into a claim limitation because such reliance indicates use of the preamble to define, in part, the claimed invention.[1]

This proposition should not be controversial. The above quote and citation appear verbatim in the current Manual of Patent Examining Procedure (MPEP) at §2111.02, a copy of which is attached as **Exhibit A**. The above quote and citation also appear verbatim in the subsequent Federal Circuit cases *In Re Cruciferous Sprout Litigation*, 301 F.3d 1343, 1347 (Fed. Cir. 2002), and *Invitrogen v. Biocrest*, 327 F.3d 1364, 1370 (Fed. Cir. 2003). Moreover, Fulbright & Jaworski actually relied on the preamble of claim 1 *in this case* – "A method of treating a pathophysiological state caused by a toxic mediator-related disease" – to distinguish U.S. Patent 4,874,522 to Okamoto during the prosecution of the 418 patent. For example, in the June 17, 1996 Response (at APX. 59), Fulbright & Jaworski argued:

> Finally, the Examiner states that 'Okamoto et al. disclose a method of continuous arteriovenous hemofiltration of animals with microglobulin which may cause sepsis, shock or multiorgan system failure.' Applicants contend that, contrary to the Examiner's statement, B2MG [microglobulin] has no known rule [sic] in sepsis, shock or multiorgan system failure. As stated in the declarations of Drs. Lee and Matson, their clinical and research work has focused on sepsis, shock, SIRS and multiorgan system failure; however, they know of no causal association between B2MG and sepsis, shock, SIRS or MOSF, nor are they aware that such an association exists.

The 418 patent explains that "sepsis, shock or multiorgan system failure" are "toxic mediator-related diseases" as set forth in the preamble (but not body) of claim 1. *See*, e.g., 1:35-55 (APX. 7). The declarations under 37 C.F.R. §1.132 submitted by Drs.

---

[1] *Catalina Marketing*, 289 F.3d at 808.

Lee and Matson with the June 17, 1996 Response (attached as **Exhibit B**) repeat this argument, and in the July 15, 1996 Office Action (attached as **Exhibit C**), the Examiner accepted this argument to overcome the rejection based on U.S. Patent No. 4,874,522 to Okamoto:

> 1. The declaration under 37 C.F.R. § 1.132 filed 6/21/96 is sufficient to overcome the rejection of claims 1-8 based upon U.S. Patent No. 4,874,522.

Not only do Federal Circuit case law and the PTO's MPEP show that it was permissible for Fulbright & Jaworski to argue during prosecution that the preamble of claim 1 distinguished over the prior art, but Fulbright & Jaworski actually made such an argument that was accepted by the Examiner *in this case.* Mr. Kirk should not be permitted to testify otherwise now.

C. Kirk's Statements that the Understanding of One Skilled in the Art is Irrelevant to a Negative Limitation analysis are also Contradicted by the Case Law, and are Therefore Inadmissible.

Fulbright & Jaworski argues again that *in this case* there is no support to be found for adding a negative limitation. Fulbright & Jaworski's and Kirk's search for support fails because they again misconstrue the law and ignore the facts. Patents are written for an audience of those skilled in the art; here, what a skilled artisan would see in the patent is critically important to the analysis.

A negative limitation analysis is merely a special case of a written description analysis under 35 USC §112, ¶1, as explained in *Ex Parte Parks* cited in Immunocept's opening brief. To meet the statutory written description requirement, "a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention." MPEP at §2163(I) (attached as **Exhibit D**), *citing Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1319, 66 USPQ2d 1429, 1438 (Fed. Cir. 2003; *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563 (Fed. Cir. 1991). The relevant question here is whether the originally filed disclosure of the '418 patent specification would have conveyed to one skilled in the art the concept of performing filtration of whole blood to treat toxic mediator-related disease without the addition of heat – not, as Fulbright & Jaworski would have it, whether the negative limitation is explicitly disclosed in the specification. In the deposition testimony cited in Immunocept's opening brief, Mr. Kirk focuses only on the specification, and he ignores what one skilled in the art would understand the specification to convey. Since this is wrong as a matter of law, Kirk should not be permitted to testify that the understanding of one skilled in the art is irrelevant to this issue.

D, Speculation is not a Proper Subject for Expert Testimony.

Kirk argues that the Examiner must have relied on the "consisting of" amendment to distinguish the Nosé plasma cholesterol filtration patent based on the heating step disclosed in Nosé. *In this case* there is absolutely no foundation in the record to support such speculation. Kirk persists despite: (1) the absence of argument by Fulbright & Jaworski regarding the "consisting of" language when the amendment was submitted; (2) the explicit argument by Fulbright & Jaworski during prosecution that Nosé is distinguishable based on the molecular weight exclusion limit of the claimed filter; (3) the absence of any statement from the Examiner regarding the "consisting of" language or the Nosé heating step; and (4) the Examiner's explicit statement that Dr. Lee's declaration regarding the claimed filter's molecular weight exclusion limit was sufficient to distinguish Nosé. Mr. Kirk's argument is therefore sheer speculation that is not the proper subject for expert testimony.

III
Conclusion

Plaintiffs respectfully request that the Court sustain Plaintiffs' objections and exclude the proffered testimony of Mr. Kirk pursuant to Federal Rule of Evidence 702.

Respectfully submitted,

Michael P. Lynn, P.C.
State Bar No. 12738500
Jeffrey M. Tillotson, P.C.
State Bar No. 20039200
John Volney
State Bar No. 24003118
Jeremy A. Fielding
State Bar No. 24040895
Lynn Tillotson & Pinker, LLP
750 N. St. Paul Street, Suite 1400
Dallas, Texas 75201
(214) 981-3800 Telephone
(214) 981-3839 Facsimile

ATTORNEYS FOR PLAINTIFFS

IMMUNOCEPT, LLC
PATRICE ANN LEE
JAMES REESE MATSON

CERTIFICATE OF SERVICE

The undersigned hereby certifies that a true and correct copy of the above and foregoing document has been served as shown below on this the 10th day of March 2006:

Via Facsimile
David J. Beck, Esq.
Geoff Gannaway, Esq.
Beck, Redden & Secrest, L.L.P.
One Houston Center
1221 McKinney Street, Suite 4500
Houston, Texas 77010
(713) 951-3700 Telephone
(713) 951-3720 Facsimile
Attorneys for Fulbright & Jaworski, LLP

Jeremy A. Fielding

Exhibit A

1029, 1033 (Fed. Cir. 1999) and MPEP § 2173.05(a).<

2111.02 *>Effect< of Preamble [R-1]

>The determination of whether a preamble limits a claim is made on a case-by-case basis in light of the facts in each case; there is no litmus test defining when a preamble limits the scope of a claim. *Catalina Mktg. Int'l v. Coolsavings.com, Inc.*, 289 F.3d 801, 808, 62 USPQ2d 1781, 1785 (Fed. Cir. 2002). See *id.* at 808-10, 62 USPQ2d at 1784-86 for a discussion of guideposts that have emerged from various decisions exploring the preamble's effect on claim scope, as well as a hypothetical example illustrating these principles.<

"[A] claim preamble has the import that the claim as a whole suggests for it." *Bell Communications Research, Inc. v. Vitalink Communications Corp.*, 55 F.3d 615, 620, 34 USPQ2d 1816, 1820 (Fed. Cir. 1995). "If the claim preamble, when read in the context of the entire claim, recites limitations of the claim, or, if the claim preamble is 'necessary to give life, meaning, and vitality' to the claim, then the claim preamble should be construed as if in the balance of the claim." *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165-66 (Fed. Cir. 1999). See also *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951) (A preamble reciting "An abrasive article" was deemed essential to point out the invention defined by claims to an article comprising abrasive grains and a hardened binder and the process of making it. The court stated "it is only by that phrase that it can be known that the subject matter defined by the claims is comprised as an abrasive article. Every union of substances capable *inter alia* of use as abrasive grains and a binder is not an 'abrasive article.'" Therefore, the preamble served to further define the structure of the article produced.).

PREAMBLE STATEMENTS LIMITING STRUCTURE

Any terminology in the preamble that limits the structure of the claimed invention must be treated as a claim limitation. See, e.g., *Corning Glass Works v. Sumitomo Elec. U.S.A., Inc.*, 868 F.2d 1251, 1257, 9 USPQ2d 1962, 1966 (Fed. Cir. 1989) (The determination of whether preamble recitations are structural limitations can be resolved only on review of the entirety of the application "to gain an understanding of what the inventors actually invented and intended to encompass by the claim."); *Pac-Tec Inc. v. Amerace Corp.*, 903 F.2d 796, 801, 14 USPQ2d 1871, 1876 (Fed. Cir. 1990) (determining that preamble language that constitutes a structural limitation is actually part of the claimed invention). See also *In re Stencel*, 828 F.2d 751, 4 USPQ2d 1071 (Fed. Cir. 1987). (The claim at issue was directed to a driver for setting a joint of a threaded collar, however the body of the claim did not directly include the structure of the collar as part of the claimed article. The examiner did not consider the preamble, which did set forth the structure of the collar, as limiting the claim. The court found that the collar structure could not be ignored. While the claim was not directly limited to the collar, the collar structure recited in the preamble did limit the structure of the driver. "[T]he framework - the teachings of the prior art - against which patentability is measured is not all drivers broadly, but drivers suitable for use in combination with this collar, for the claims are so limited." Id. at 1073, 828 F.2d at 754.).

PREAMBLE STATEMENTS RECITING PURPOSE OR INTENDED USE

The claim preamble must be read in the context of the entire claim. The determination of whether preamble recitations are structural limitations or mere statements of purpose or use "can be resolved only on review of the entirety of the [record] to gain an understanding of what the inventors actually invented and intended to encompass by the claim." *Corning Glass Works,* 868 F.2d at 1257, 9 USPQ2d at 1966. If the body of a claim fully and intrinsically sets forth all of the limitations of the claimed invention, and the preamble merely states, for example, the purpose or intended use of the invention, rather than any distinct definition of any of the claimed invention's limitations, then the preamble is not considered a limitation and is of no significance to claim construction. *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165 (Fed. Cir. 1999). See also *Rowe v. Dror*, 112 F.3d 473, 478, 42 USPQ2d 1550, 1553 (Fed. Cir. 1997) ("where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention, the preamble is not a

EXHIBIT A tabbies

Exhibit B

JUN 21 1996

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE #14 6-28-96

Serial No.:	08/271,136	§	Docket No.: D-5563-CIP
Filed:	06 July 1994	§	Examiner: S. Kim
Applicants:	Lee et al.	§	Art Unit 1306
Title:	Hemofiltration of Mediator Related Diseases	§	

Box AF
Assistant Commissioner of Patents
Washington, D.C. 20231

DECLARATION OF DR. PATRICE LEE
UNDER 37 C.F.R. 1.132

Dear Sir:

I, Patrice Anne Lee, Ph.D., do hereby depose and say as follows:

1. I have read U.S. Patent Application Serial No. 08/271,136, filed on July 6, 1994, and I am aware of its contents. Additionally, I have read U.S. Patent No. 4,874,522 to Okamoto et al. and am aware of its contents.

2. At the time of the filing of U.S. Patent Application Serial No. 08/271,136, I was the Director of Critical Care Research at Medical City Dallas Hospital. Currently, I am a Research Scientist in the Department of Pharmacology at Amgen, Incorporated in Boulder, Colorado, and a physiologist with expertise in the area of cardiopulmonary physiology, particularly in the area of septic shock and multi-organ system failure. I am skilled in the art of sepsis, septic shock, SIRS, MOSF and cardiopulmonary physiology and have observed carefully the literature in these and related fields since 1986. A *curriculum vitae* describing my experience is attached hereto.

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to Assistant Commissioner of Patents Washington, D.C. 20231 on 6-17-96
Linda A. Bourg
Linda A. Bourg 6-17-96
Signature Date

EXHIBIT B

3. U.S. Patent No. 4,874,522 to Okamoto et al. recites specific molecules that will pass or will not pass through the membrane disclosed in the specification. The following table shows various molecules, some of which were disclosed in Okamoto et al., and some of which are claimed by Applicants in U.S. Patent Application Serial No. 08/271,136. Molecular weights for the molecules are shown.

Molecules & Permeabilities

Molecule(s)	Molecular Weight (Daltons)	Claimed Permeability Performance of Okamoto Filter	Proven Permeability Performance of Okamoto Filter	Citation in Okamoto patent; Col/lines
Larger inflammatory mediators	100,000 - 150,000 Dalton	none	none	**claimed by Applicants**
albumin	68,000	<=10% passed; (i.e. minimal permeability)	0% passed	17/56-57; 12/46-47; 13/27; 14/56-57
β2-micro-globulin	11,600	0% passed	0% passed	17/61; 19/5-7; 20/4-7; 12/64-65 14/55-58
inulin	5000	> or = 50% passed; (i.e. large permeability)	80 to 95% passed	17/56-57; 12/15; 12/64-65
pyrogens	2000 - 17,000	no claims made	0% passed	12/18-19; 12/67-68

As summarized in the table above, the membrane disclosed and claimed in U.S. Patent No. 4,874,522 to Okamoto et al. will *not* pass B2MG, a molecule having a MW of 11,600 Daltons. Thus, only molecules *smaller* than 11,600 Daltons, such as inulin, are passed by the membrane disclosed in the Okamoto et al. patent.

4. "Microglobulin", including ß2-microglobin (ß2MG), has no known causal role or any pathogenic role in sepsis, shock or multiorgan system failure. The indexes of more than ten well-known textbooks of medicine, nephrology, and laboratory medicine were reviewed for all listings of ß2MG, specifically concerning any association with sepsis, shock or multiorgan system failure. None of these books reported an association of ß2MG with sepsis, shock or multiorgan system failure.

In addition, four standard texts were reviewed and the diseases or conditions with which ß2MG is associated are tabulated below:

Role of ß2MG in Human Disease

Primary Disease/Condition	Role of ß2MG	Source; page #
HLA tissue antigen	Class I molecule	1;1965
Multiple Myeloma	prognostic indicator, no primary role	1;1030
tubulointerstitial renal disease	marker of tubular proteinuria, not primarily pathogenic	1;521
Amyloidosis of End Stage Renal Disease	primary component of deposits	2;225
Chronic Lymphocytic leukemia	prognostic indicator, no primary role	3;644-5
AIDS	prognostic indicator, no primary role	3;644-5
Heavy metal poisoning	prognostic indicator, no primary role	4;704

1. Cecil Textbook of Medicine, J.B. Wyngaarden, M.D. and L.H. Smith, Jr., M.D., Editors; W.B. Saunders Co. 1988.
2. Principles and Practice of Dialysis, W.L. Henrich, M.D., Editor; Williams & Wilkins, 1994.
3. Laboratory Test Handbook, 3rd Edition, D.S. Jacobs et al.
4. Toxicology, Second Edition, Doull et al., Editors, 1980

ß2MG is discussed in many medical reference books, of which the preceding table presents a typical sample. None of the medical texts or references reviewed suggest any pathogenic role of ß2MG in any disease, except Amyloidosis of End Stage Renal Disease. In all other diseases discussed, ß2MG is important only as a marker of disease activity, and is not ascribed any disease-causing role. Moreover, the same texts contain brief to lengthy discussions of sepsis, SIRS, shock and multiorgan failure, yet none mention ß2MG in these discussions.

5. The following review articles on sepsis, SIRS, multiorgan failure were examined to determine whether a role for ß2MG in sepsis, SIRS, or multiorgan failure was disclosed. No mention of ß2MG was made.

Review Articles on Sepsis, SIRS, MOSF

Title	Author	Journal
Handbook of Mediators in Septic Shock	E.A. Neugebauer, J.W. Holaday, Eds	
Toward a theory regarding the pathogenesis of the systemic inflammatory response syndrome: What we do and do not know about cytokine regulation	Roger C. Bone, M.D.	Critical Care Medicine, January 1996
Sepsis in the critically ill patient- in brief.	C.C. Baker & T. Huynh	Current Problems in Surgery, 1995

6. I have been active in clinical and basic research work focused on sepsis, septic shock, SIRS, and MOSF for over 10 years. I know of no causal association between ß2MG and sepsis, septic shock, SIRS, or MOSF, nor am I aware of any theory that such an assocation exists. Further, I know of no reason to believe that ß2MG is useful as an indicator of activity in sepsis, septic shock, SIRS, and MOSF; I am aware that ß2MG does appear to be a nonspecific and noncausal indicator of activity in some inflammatory diseases.

7. I hereby declare that all statements herein of my own knowledge are true, that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both under § 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the applications or any patent issued therein.

Date: 13 Jun 1996

Patrice Anne Lee, Ph.D.

Initial Review
BOX
MAIL ROOM JUN 21 1996 PATENT & TRADEMARK

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Serial No.:	08/271,136	§ Docket No.: D-5563-CIP
Filed:	06 July 1994	§ Examiner: S. Kim
Applicants:	Lee et al.	§ Art Unit 1306
Title:	Hemofiltration of Mediator Related Diseases	§

Box AF
Assistant Commissioner of Patents
Washington, D.C. 20231

DECLARATION OF DR. JAMES R. MATSON UNDER 37 C.F.R. 1.132

Dear Sir:

I, James R. Matson, M.D., do hereby depose and say as follows:

1. I have read U.S. Patent Application Serial No. 08/271,136, filed on July 6, 1994, and I am aware of its contents. Additionally, I have read U.S. Patent No. 4,874,522 to Okamoto et al. and am aware of its contents.

2. Currently, I am a Pediatric Critical Care Physician at Medical City Dallas Hospital, Dallas, Texas, with expertise in the area of cardiopulmonary physiology, particularly in the area of septic shock and multi-organ system failure. I am skilled in the art of sepsis, septic shock, SIRS, MOSF and cardiopulmonary physiology and have observed carefully the literature in these and related fields since 1978. A *curriculum vitae* describing my experience is attached hereto.

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in a n envelope addressed to Assistant Commissioner of Patents Washington, D.C. 20231 on 6-17-96
Linda A. Bourg
Linda A. Bourg (Signature) 6-17-96 (Date)

3. U.S. Patent No. 4,874,522 to Okamoto et al. recites specific molecules that will pass or will not pass through the membrane disclosed in the specification. The following table shows various molecules, some of which were disclosed in Okamoto et al., and some of which are claimed by Applicants in U.S. Patent Application Serial No. 08/271,136. Molecular weights for the molecules are shown.

Molecules & Permeabilities

Molecule(s)	Molecular Weight (Daltons)	Claimed Permeability Performance of Okamoto Filter	Proven Permeability Performance of Okamoto Filter	Citation in Okamoto patent; Col/lines
Larger inflammatory mediators	100,000 - 150,000 Dalton	none	none	**claimed by Applicants**
albumin	68,000	<=10% passed; (i.e. minimal permeability)	0% passed	17/56-57; 12/46-47; 13/27; 14/56-57
β2-micro-globulin	11,600	0% passed	0% passed	17/61; 19/5-7; 20/4-7; 12/64-65 14/55-58
inulin	5000	> or = 50% passed; (i.e. large permeability)	80 to 95% passed	17/56-57; 12/15; 12/64-65
pyrogens	2000 - 17,000	no claims made	0% passed	12/18-19; 12/67-68

As summarized in the table above, the membrane disclosed and claimed in U.S. Patent No. 4,874,522 to Okamoto et al. will *not* pass B2MG, a molecule having a MW of 11,600 Daltons. Thus, only molecules *smaller* than 11,600 Daltons, such as inulin, are passed by the membrane disclosed in the Okamoto et al. patent.

4. "Microglobulin", including ß2-microglobin (ß2MG), has no known causal role or any pathogenic role in sepsis, shock or multiorgan system failure. The indexes of more than ten well-known textbooks of medicine, nephrology, and laboratory medicine were reviewed for all listings of ß2MG, specifically concerning any association with sepsis, shock or multiorgan system failure. None of these books reported an association of ß2MG with sepsis, shock or multiorgan system failure.

In addition, four standard texts were reviewed and the diseases or conditions with which ß2MG is associated are tabulated below:

Role of ß2MG in Human Disease

Primary Disease/Condition	Role of ß2MG	Source; page #
HLA tissue antigen	Class I molecule	1;1965
Multiple Myeloma	prognostic indicator, no primary role	1;1030
tubulointerstitial renal disease	marker of tubular proteinuria, not primarily pathogenic	1;521
Amyloidosis of End Stage Renal Disease	primary component of deposits	2;225
Chronic Lymphocytic leukemia	prognostic indicator, no primary role	3;644-5
AIDS	prognostic indicator, no primary role	3;644-5
Heavy metal poisoning	prognostic indicator, no primary role	4;704

1. Cecil Textbook of Medicine, J.B. Wyngaarden, M.D. and L.H. Smith, Jr., M.D., Editors; W.B. Saunders Co. 1988.
2. Principles and Practice of Dialysis, W.L. Henrich, M.D., Editor; Williams & Wilkins, 1994.
3. Laboratory Test Handbook, 3rd Edition, D.S. Jacobs et al.
4. Toxicology, Second Edition, Doull et al., Editors, 1980

ß2MG is discussed in many medical reference books, of which the preceding table presents a typical sample. None of the medical texts or references reviewed suggest any pathogenic role of ß2MG in any disease, except Amyloidosis of End Stage Renal

Disease. In all other diseases discussed, ß2MG is important only as a marker of disease activity, and is not ascribed any disease-causing role. Moreover, the same texts contain brief to lengthy discussions of sepsis, SIRS, shock and multiorgan failure, yet none mention ß2MG in these discussions.

5. The following review articles on sepsis, SIRS, multiorgan failure were examined to determine whether a role for ß2MG in sepsis, SIRS, or multiorgan failure was disclosed. No mention of ß2MG was made.

Review Articles on Sepsis, SIRS, MOSF

Title	Author	Journal
Handbook of Mediators in Septic Shock	E.A. Neugebauer, J.W. Holaday, Eds	
Toward a theory regarding the pathogenesis of the systemic inflammatory response syndrome: What we do and do not know about cytokine regulation	Roger C. Bone, M.D.	Critical Care Medicine, January 1996
Sepsis in the critically ill patient-in brief.	C.C. Baker & T. Huynh	Current Problems in Surgery, 1995

6. I have been active in clinical and basic research work focused on sepsis, septic shock, SIRS, and MOSF for over 10 years. I know of no causal association between ß2MG and sepsis, septic shock, SIRS, or MOSF, nor am I aware of any theory that such an assocation exists. Further, I know of no reason to believe that ß2MG is useful as an indicator of activity in sepsis, septic shock, SIRS, and MOSF; I am aware that ß2MG does appear to be a nonspecific and noncausal indicator of activity in some inflammatory diseases.

7. I hereby declare that all statements herein of my own knowledge are true, that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both under § 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the applications or any patent issued therein.

Date: 6/13/96

James R. Matson, M.D.

Exhibit C

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
~~08/251,201~~	~~05/31/94~~	~~MISCUITTA~~	~~BRODGE, J~~

13M1/0708

~~FITZPATRICK CELLA HARPER & SCINTO~~
~~277 PARK AVENUE~~
~~NEW YORK NY 10172~~

EXAMINER	

ART UNIT	PAPER NUMBER

07/08/96

DATE MAILED:

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☑ This application has been examined ☑ Responsive to communication filed on 6/21/96 ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 2 month(s), —— days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☐ Notice of References Cited by Examiner, PTO-892.
2. ☐ Notice of Draftsman's Patent Drawing Review, PTO-948.
3. ☐ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ ______

Part II SUMMARY OF ACTION

1. ☑ Claims 1-8 are pending in the application.

   Of the above, claims ______ are withdrawn from consideration.

2. ☐ Claims ______ have been cancelled.
3. ☑ Claims 1-8 are allowed.
4. ☐ Claims ______ are rejected.
5. ☐ Claims ______ are objected to.
6. ☐ Claims ______ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☑ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on ______. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on ______, has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed ______, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. ______; filed on ______.
13. ☑ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXHIBIT
C

EXAMINER'S ACTION

Exhibit D

law. They are designed to assist Office personnel in analyzing claimed subject matter for compliance with substantive law. Rejections will be based upon the substantive law, and it is these rejections which are appealable. Consequently, any perceived failure by Office personnel to follow these Guidelines is neither appealable nor petitionable.

These Guidelines are intended to form part of the normal examination process. Thus, where Office personnel establish a prima facie case of lack of written description for a claim, a thorough review of the prior art and examination on the merits for compliance with the other statutory requirements, including those of 35 U.S.C. 101, 102, 103, and 112, is to be conducted prior to completing an Office action which includes a rejection for lack of written description.

I. GENERAL PRINCIPLES GOVERNING COMPLIANCE WITH THE "WRITTEN DESCRIPTION" REQUIREMENT FOR APPLICATIONS

The first paragraph of 35 U.S.C. 112 requires that the "specification shall contain a written description of the invention * * *." This requirement is separate and distinct from the enablement requirement. See, e.g., *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1560, 19 USPQ2d 1111, 1114 (Fed. Cir. 1991). >See also *Univ. of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 920-23, 69 USPQ2d 1886, 1890-93 (Fed. Cir. 2004) (discussing history and purpose of the written description requirement); *In re Curtis*, 354 F.3d 1347, 1357, 69 USPQ2d 1274, 1282 (Fed. Cir. 2004) ("conclusive evidence of a claim's enablement is not equally conclusive of that claim's satisfactory written description").< The written description requirement has several policy objectives. "[T]he 'essential goal' of the description of the invention requirement is to clearly convey the information that an applicant has invented the subject matter which is claimed." *In re Barker*, 559 F.2d 588, 592 n.4, 194 USPQ 470, 473 n.4 (CCPA 1977). Another objective is to put the public in possession of what the applicant claims as the invention. See *Regents of the University of California v. Eli Lilly*, 119 F.3d 1559, 1566, 43 USPQ2d 1398, 1404 (Fed. Cir. 1997), *cert. denied*, 523 U.S. 1089 (1998). The written description requirement of the Patent Act promotes the progress of the useful arts by ensuring that patentees adequately describe their inventions in their patent specifications in exchange for the right to exclude others from practicing the invention for the duration of the patent's term.

To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. See, e.g., >*Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1319, 66 USPQ2d 1429, 1438 (Fed. Cir. 2003);< *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d at 1563, 19 USPQ2d at 1116. However, a showing of possession alone does not cure the lack of a written description. *Enzo Biochem, Inc. v. Gen-Probe, Inc.*, **>323 F.3d 956, 969-70,< 63 USPQ2d 1609, 1617 (Fed. Cir. 2002). Much of the written description case law addresses whether the specification as originally filed supports claims not originally in the application. The issue raised in the cases is most often phrased as whether the original application provides "adequate support" for the claims at issue or whether the material added to the specification incorporates "new matter" in violation of 35 U.S.C. 132. The "written description" question similarly arises in the interference context, where the issue is whether the specification of one party to the interference can support the newly added claims corresponding to the count at issue, i.e., whether that party can "make the claim" corresponding to the interference count. See, e.g., *Martin v. Mayer*, 823 F.2d 500, 503, 3 USPQ2d 1333, 1335 (Fed. Cir. 1987). In addition, early opinions suggest the Patent and Trademark Office was unwilling to find written descriptive support when the only description was found in the claims; however, this viewpoint was rejected. See *In re Koller*, 613 F.2d 819, 204 USPQ 702 (CCPA 1980) (original claims constitute their own description); accord *In re Gardner*, 475 F.2d 1389, 177 USPQ 396 (CCPA 1973); *accord In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976). It is now well accepted that a satisfactory description may be in the claims or any other portion of the originally filed specification. These early opinions did not address the quality or specificity of particularity that was required in the description, i.e., how much description is enough.

An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as

EXHIBIT
tabbies
D

words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997). Possession may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was "ready for patenting" such as by the disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention. See, e.g., *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 68, 119 S.Ct. 304, 312, 48 USPQ2d 1641, 1647 (1998); *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406; *Amgen, Inc. v. Chugai Pharmaceutical*, 927 F.2d 1200, 1206, 18 USPQ2d 1016, 1021 (Fed. Cir. 1991) (one must define a compound by "whatever characteristics sufficiently distinguish it"). "Compliance with the written description requirement is essentially a fact-based inquiry that will 'necessarily vary depending on the nature of the invention claimed.'" *Enzo Biochem*, **>323 F.3d at 963<, 63 USPQ2d at 1613. An application specification may show actual reduction to practice by describing testing of the claimed invention or, in the case of biological materials, by specifically describing a deposit made in accordance with 37 CFR 1.801 *et seq.* See *Enzo Biochem*, **>323 F.3d at 965<, 63 USPQ2d at 1614 ("reference in the specification to a deposit may also satisfy the written description requirement with respect to a claimed material"); see also Deposit of Biological Materials for Patent Purposes, Final Rule, 54 FR 34,864 (August 22, 1989) ("The requirement for a specific identification is consistent with the description requirement of the first paragraph of 35 U.S.C. 112, and to provide an antecedent basis for the biological material which either has been or will be deposited before the patent is granted." Id. at 34,876. "The description must be sufficient to permit verification that the deposited biological material is in fact that disclosed. Once the patent issues, the description must be sufficient to aid in the resolution of questions of infringement." Id. at 34,880.). Such a deposit is not a substitute for a written description of the claimed invention. The written description of the deposited material needs to be as complete as possible because the examination for patentability proceeds solely on the basis of the written description. See, e.g., *In re Lundak*, 773 F.2d 1216, 227 USPQ 90 (Fed. Cir. 1985). See also 54 FR at 34,880 ("As a general rule, the more information that is provided about a particular deposited biological material, the better the examiner will be able to compare the identity and characteristics of the deposited biological material with the prior art.").

A question as to whether a specification provides an adequate written description may arise in the context of an original claim which is not described sufficiently (see, e.g., *Enzo Biochem*, **>323 F.3d at 968<, 63 USPQ2d at 1616 (Fed. Cir. 2002); *Eli Lilly*, 119 F.3d 1559, 43 USPQ2d 1398), a new or amended claim wherein a claim limitation has been added or removed, or a claim to entitlement of an earlier priority date or effective filing date under 35 U.S.C. 119, 120, or 365(c). Most typically, the issue will arise in the context of determining whether new or amended claims are supported by the description of the invention in the application as filed (see, e.g., *In re Wright*, 866 F.2d 422, 9 USPQ2d 1649 (Fed. Cir. 1989)), whether a claimed invention is entitled to the benefit of an earlier priority date or effective filing date under 35 U.S.C. 119, 120, or 365(c) (see, e.g., *New Railhead Mfg. L.L.C. v. Vermeer Mfg. Co.*, 298 F.3d 1290, 63 USPQ2d 1843 (Fed. Cir. 2002); *Tronzo v. Biomet, Inc.*, 156 F.3d 1154, 47 USPQ2d 1829 (Fed. Cir. 1998); Fiers v. Revel, 984 F.2d 1164, 25 USPQ2d 1601 (Fed. Cir. 1993); *In re Ziegler*, 992 F.2d 1197, 1200, 26 USPQ2d 1600, 1603 (Fed. Cir. 1993)), or whether a specification provides support for a claim corresponding to a count in an interference (see, e.g., *Fields v. Conover*, 443 F.2d 1386, 170 USPQ 276 (CCPA 1971)). Compliance with the written description requirement is a question of fact which must be resolved on a case-by-case basis. *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d at 1563, 19 USPQ2d at 1116 (Fed. Cir. 1991).

A. Original Claims

There is a strong presumption that an adequate written description of the claimed invention is present when the application is filed. *In re Wertheim*, 541 F.2d 257, 263, 191 USPQ 90, 97 (CCPA 1976) ("we are of the opinion that the PTO has the initial burden of presenting evidence or reasons why persons skilled in the art would not recognize in the disclosure a description of the invention defined by the claims"). However, as